



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,020	03/27/2003	Amarjit Singh	U 013943-5	9010

140 7590 03/20/2006

LADAS & PARRY
26 WEST 61ST STREET
NEW YORK, NY 10023

EXAMINER

PRYOR, ALTON NATHANIEL

ART UNIT	PAPER NUMBER
----------	--------------

1616

DATE MAILED: 03/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,020

Applicant(s)

SINGH ET AL.

Examiner

Alton N. Pryor

Art Unit

1616

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 01 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1,2,4-11,15,17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,2,4-11,15 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/27/03; 4/22/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

- I. **Rejection of claims 1,2,4-11,15,17 under 35 USC 112, 1st paragraph in regard to “pharmaceutical composition of Nimisulide” will not be maintained.** Claims have been amended to claim the “tablet composition” instead of the general “composition”.
- II. **Rejection of claims 1,2,4-11,15,17 under 35 USC 112, 1st paragraph with respect to “methacrylic acid derivatives” will not be maintained.** The term “derivative” has been deleted from the claims.
- III. **Rejection of claims 1,2,4-11,15,17 under 35 USC 112, 1st paragraph with respect to “fraction” will not be maintained.** The term “fraction” has been replaced by the term “layer”.
- IV. **Applicant’s arguments, see paper, filed 8/1/20, with respect to the rejection(s) of claim(s) 1,2,4-11,15,17 under 35 USC 112, 1st paragraph have been fully considered and are persuasive.** Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1616

Claims 1,2,4-11,15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Skinhoj (WO 99/12524; 3/18/99). Skinhoj teaches a composition of an NSAID for peroral use comprising a fast release layer and an extended release layer, wherein said NSAID is present in both layers and in an amount ranging from 1 to 1600 mg. Skinhoj teaches that such a composition reduces the dose amount of active required on a daily bases as compared to a plain tablet. Skinhoj teaches that the composition can comprise a control release material such as cellulose derivatives, and excipients, plasticizers, calcium carbonate and fatty acids. Skinhoj teaches that the composition can exist in tablet form. Skinhoj teaches a number of NSAIDs including nimesulide. See abstract, page 19 line 22 – page 20 line 27, page 21 lines 19-21, page 26 lines 28-29, page 35 lines 15-24, page 36 line 25 – page 38 line 32, claims 1, 11. Skinhoj does not disclose an example where nimesulide is employed in the composition / tablet. It would have been obvious to one having ordinary skill in the art to have employed nimesulide in the tablet / composition. One would have been motivated to do this in order to decrease the dosage amount of nimesulide given to a patient.

Telephonic Inquiry

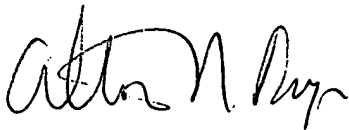
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

Art Unit: 1616

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Alton N. Pryor', is positioned above the printed name.

Alton Pryor
Primary Examiner
AU 1616